REMARKS

This paper is provided in response to the final Office Action mailed May 1, 2007, and Advisory Action mailed August 22, 2007. This Amendment and Response is accompanied by a Request for Continuing Examination.

Claims 1–10 are currently pending. Claim 1 is amended to incorporated the subject matter of claim 2. Claim 3 is amended for grammatical correction. Claims 2 and 11–17 canceled herewith without prejudice. These amendments are supported throughout the specification. No new matter is added. Reconsideration and allowance are requested for the following reasons.

Rejection under 35 U.S.C. § 112

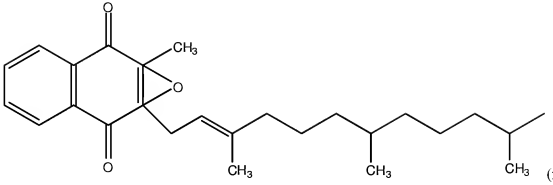
Claims 1 and 3 were rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. Applicants respectfully traverse the rejection. Without acquiescing in the rejection, Applicants note that claim 1 has been amended to recite a method of treatment of dermatological lesions using vitamin K1 oxide. The Office Action concedes that the specification shows how vitamin K1 oxide is suitable for the treatment of bruises and spider veins. Therefore, the specification clearly demonstrates how to make and use the invention of claim 1 (and claim 3 which depends from claim 1), and the enablement requirement has been met. Withdrawal of the rejection is requested.

Rejection under 35 U.S.C. § 103

Claims 1–17 were rejected under 35 U.S.C. § 103(a) as unpatentable over Elson (WO 97/39746) in view of Elson (US 5,510,391), further in view of Crandall (US 5,945,409). Applicants respectfully traverse the rejection.

Additionally, the rejection asserted that the previously supplied declaration supporting surprising results was deficient. Applicants respectfully disagree.

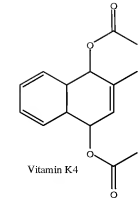
Claim 1, as presently amended, is directed to the use of



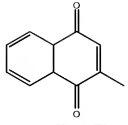
(formula I)

for treatment of dermatological lesions. The method of claim 1 is accurately represented by testing of the above-represented K1 oxide in "Auriderm XO" in the Declaration of Dr. Karavani. The results demonstrate that the "XO" cream containing above-represented K1 oxide was more effective in patients undergoing blepharophasty as demonstrated by reduced bruising of the delicate tissue surrounding the eyes. See, table on page 5 showing significantly lower bruising scores for patients using above-represented K1 oxide versus vitamin K. Applicant's disagree with the statement in the Office Action that "the prior art shows better results for this evaluation." No explanation or basis for disputing the Declaration has been presented by the Office.

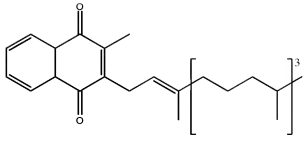
The Office also objects to the study presented in Dr. Karavani's declaration because it does not also compare vitamin K1 oxide with another vitamin K1 analog in addition to vitamin K1. Structures for vitamin K1, K2, K3, K4, K5 and K6 are provided below to assist structural understanding vitamin K1 oxide to vitamin K1 to other vitamin K analogs. Applicants disagree that a showing of another vitamin K1 analog is required to distinguish Elson. Elson does not describe *vitamin **K1** analogs.* Elson WO '746 and Elson '391 patent discloses the existence of synthetic *vitamin **K*** analogs, such as K3, K4, K5, K6, and K7. Elson WO '746 suggests using vitamins K1 or K2. However, synthetic vitamin K analogs, e.g., K3 and K4, etc… are toxic, consequently they cannot be used in pharmaceutical or cosmetic compositions. In contrast, vitamin K1 is naturally occurring, found in sources such as leafy green vegetables. Therefore, the comparative analysis between vitamin K1 and the above-presented vitamin K1 oxide is the appropriate comparison to demonstrate enhanced results over Elson.



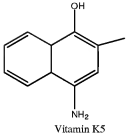
Vitamin K4



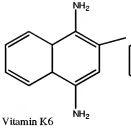
Vitamin K3



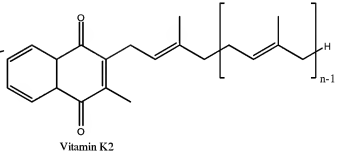
Vitamin K1



Vitamin K5



Vitamin K6



Vitamin K2

Applicants submit that the Office Action does not make a *prima facie* case of obviousness, because all the limitations of the present claims 1 and 3–10 are not taught by the combination of references cited in the Office Action. Applicants note that claims 11–17 are cancelled without prejudice.

To make a *prima facie* case of obviousness, the teachings of the prior art should have suggested the claimed subject matter to the person of ordinary skill in the art, and all the claim limitations must be taught or suggested in the references cited by the Examiner. *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000). As articulated by the Supreme Court in a recent case, a combination is obvious if it is no more than the predictable use of known elements according to their established functions; and there was a reason to combine the known elements. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. __ (2007). To make a *prima facie* case of obviousness, "it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." *Id.*

Claim 1 as amended recites a method for the treatment of dermatological lesions by submitting a lesion to a composition comprising the compound of formula I in a pharmaceutical or cosmetic carrier. Claims 3–10 depend from claim 1 and incorporate all the limitations thereof. Elson (WO) teaches the use of vitamin K1 in a cream formulation, wherein the formulation also contains ethyl alcohol and lecithin. However, as conceded in the Office Action, Elson (WO) does not teach the use of a formulation comprising a compound of the specific formula shown in the present claims (i.e. vitamin K1 oxide). Instead, the Office Action contends that Elson ('391) suggests the equivalency of all vitamin K1 analogs and pharmaceutical formulations used for skin treatment. Applicants disagree with this contention and submit that the vitamin K1 oxide of the present claims is not encompassed by the *vitamin **K*** analogs taught in Elson ('391). In fact, the reference specifically indicates that the analogs of vitamin K are limited to the known synthetic analogues which currently include vitamins K3, K4, K5, K6 and K7 (*see* Elson '391, at col. 1, ll. 37–39). There is no teaching or suggestion in Elson ('391) that vitamin K1 oxide was considered an "analogue" of vitamin K.

Given the differences between Vitamin K1 oxide and vitamin K1, a person of skill in the art would not consider a vitamin K1 formulation an "analogue" of a vitamin K1 oxide formulation. In addition to structural differences, vitamin K1 oxide is not metabolized or broken down by exposure to light, and therefore, formulations of vitamin K1 oxide would have different skin treatment properties than formulations of vitamin K1 in the native form. Therefore, the two Elson references cited by the Examiner do not teach a composition comprising vitamin K1 oxide, and therefore, all the limitations of the present claims are not disclosed and no prima facie case of obviousness has been made. Applicants submit that the Crandall reference does not remedy the deficiencies of the two Elson references.

As the references cited by the Examiner do not disclose all the claim limitations, no *prima facie* case of obviousness has been made, and withdrawal of the rejection is respectfully requested.

SUMMARY

Favorable reconsideration in the form of a Notice of Allowance is requested. The Examiner is invited to contact Applicants' representative at the below-listed telephone number, if it is believed that prosecution of this application may be assisted. Please contact the undersigned with any questions regarding this application.

Respectfully submitted,
MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: October 31, 2007

/Anne M. Murphy/
By: Anne M. Murphy
Reg. No. 54,327